108TH CONGRESS
1ST SESSION

S. 722

To amend the Federal Food, Drug, and Cosmetic Act to require that manufacturers of dietary supplements submit to the Food and Drug Administration reports on adverse experiences with dietary supplements, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 26, 2003

Mr. DURBIN introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require that manufacturers of dietary supplements submit to the Food and Drug Administration reports on adverse experiences with dietary supplements, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Dietary Supplement Safety Act of 2003''.

SEC. 2. ADVERSE EXPERIENCES WITH DIETARY SUPPLEMENTS.

(a) IN GENERAL.—Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amended by adding at the end the following:

"SEC. 416. ADVERSE EXPERIENCES WITH DIETARY SUPPLEMENTS.

"(a) DEFINITIONS.—In this section:

"(1) ADVERSE DIETARY SUPPLEMENT EXPERIENCE.—The term 'adverse dietary supplement experience' means an adverse event that is associated with the use of a dietary supplement in a human, without regard to whether the event is known to be causally related to the dietary supplement.

"(2) SERIOUS ADVERSE DIETARY SUPPLEMENT EXPERIENCE.—The term 'serious adverse dietary supplement experience' means an adverse dietary supplement experience that—

"(A) results in—

"(i) death;

"(ii) a life-threatening condition;

"(iii) inpatient hospitalization or prolongation of hospitalization;

"(iv) a persistent or significant disability or incapacity; or

''(v) a congenital anomaly, birth defect, or other effect regarding pregnancy, including premature labor or low birth weight; or

''(B) requires medical or surgical intervention to prevent 1 of the outcomes described in subparagraph (A).

''(b) REPORTING AND REVIEW.—

''(1) SERIOUS ADVERSE DIETARY SUPPLEMENT EXPERIENCES.—

''(A) IN GENERAL.—Each manufacturer of a dietary supplement, and each packer or distributor of a dietary supplement the name of which appears on the labeling of the dietary supplement—

''(i) shall develop written procedures for—

''(I) surveillance, receipt, and evaluation of information on adverse dietary supplement experiences associated with use of the dietary supplement; and

''(II) submission to the Secretary of reports under this subsection;

"(ii) as soon as practicable after, but in no event later than 15 calendar days after, initial receipt of information with respect to a serious adverse dietary supplement experience, shall submit to the Secretary—

"(I) the information; and

"(II) a copy of the current labeling for the dietary supplement;

"(iii)(I) shall promptly investigate the adverse dietary supplement experience; and

"(II)(aa) if additional information is obtained, shall submit to the Secretary a report describing the information—

"(AA) not later than 15 days after obtaining the information; or

"(BB) at the request of the Secretary; or

"(bb) if no additional information is obtained, shall maintain records of the steps taken to seek additional information.

"(B) ELIMINATION OF DUPLICATIVE REPORTING.—

"(i) IN GENERAL.—To avoid duplicative reporting under this subsection, the

Secretary may establish a procedure under which—

"(I) a packer or distributor of a dietary supplement may submit a report to the manufacturer of the dietary supplement; and

"(II) the manufacturer shall transmit the report to the Secretary.

"(ii) REQUIREMENT.—A procedure under clause (i) shall ensure that the Secretary receives reports within the applicable period of time specified in subparagraph (A).

"(C) CLINICAL EVALUATIONS BY THE SECRETARY.—

"(i) IN GENERAL.—The Secretary shall conduct a clinical evaluation of each serious adverse dietary supplement experience with a patient that is reported to the Secretary under subparagraph (A).

"(ii) UNWILLING PATIENT.—The Secretary is not required to conduct a clinical evaluation under clause (i) to the extent that any unwillingness of the patient (or the next of kin for the patient, as the case

may be) to cooperate with the evaluation makes it impracticable to conduct the evaluation.

''(2) PERIODIC ADVERSE DIETARY SUPPLEMENT EXPERIENCE REPORTING.—A manufacturer of a dietary supplement shall annually (or at such shorter intervals as the Secretary may require), in accordance with such requirements as the Secretary may establish, submit to the Secretary a report that discloses all information received with respect to adverse dietary supplement experiences not previously reported under paragraph (1).

''(3) REVIEW REGARDING ADVERSE DIETARY SUPPLEMENT EXPERIENCES.—

''(A) IN GENERAL.—Promptly after a manufacturer of a dietary supplement receives from a consumer, or obtains by any other means, any information on an adverse dietary supplement experience, the manufacturer shall review the information.

''(B) APPLICABILITY.—Subparagraph (A)—

''(i) applies to information without regard to the source of the information, foreign or domestic; and

''(ii) includes information derived from sources such as—

''(I) commercial marketing experience;

''(II) postmarketing investigations;

''(III) postmarketing surveillance;

''(IV) studies;

''(V) reports in the scientific literature; and

''(VI) unpublished scientific papers.

''(4) ADDITIONAL REPORTING REQUIREMENTS.—In addition to the requirements of paragraphs (1) and (2), the Secretary may establish such requirements regarding the reporting of information on adverse dietary supplement experiences as the Secretary determines to be appropriate to protect the public health.

''(5) WAIVERS.—The Secretary may grant a waiver from the requirement of paragraph (1), (2), or (3) with respect to a dietary supplement if the Secretary determines that compliance with the requirement is not necessary to protect the public health.

''(6) SYSTEM FOR COORDINATION OF REPORTS RECEIVED BY THE SECRETARY.—With respect to reports of adverse dietary supplement experiences submitted to the Secretary (whether required under this subsection or otherwise), the Secretary shall establish a system to—

''(A) receive the reports;

''(B) refer the reports to the appropriate officials within the Food and Drug Administration;

''(C) store and retrieve the reports;

''(D) store and retrieve records of activities carried out in response to the reports; and

''(E) carry out such other administrative functions regarding the reports as the Secretary determines to be appropriate.

''(7) DATA COLLECTION BY SECRETARY.—

''(A) IN GENERAL.—The Secretary shall carry out a program to collect data on serious adverse dietary supplement experiences, in addition to receiving reports required in this subsection.

''(B) COOPERATION.—In carrying out the program, the Secretary shall seek the cooperation of appropriate public and private entities,

including entities that respond to medical emergencies.

''(8) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection $10,000,000 for fiscal year 2003 and each fiscal year thereafter.

''(c) POSTMARKET SURVEILLANCE.—

''(1) AUTHORITY TO REQUIRE SURVEILLANCE.—The Secretary may by order require a manufacturer of a dietary supplement to conduct postmarket surveillance for the dietary supplement if the Secretary determines that there is a reasonable possibility that a use or expected use of the dietary supplement by a significant number of consumers may result in serious adverse experiences.

''(2) SURVEILLANCE PLAN.—

''(A) IN GENERAL.—Not later than 30 days after receiving from the Secretary an order under paragraph (1) to conduct surveillance for a dietary supplement, a manufacturer shall submit to the Secretary, for the approval of the Secretary, a plan for the required surveillance.

''(B) QUALIFICATIONS REGARDING SURVEILLANCE; DATA REGARDING ADVERSE DIE-

TARY SUPPLEMENT EXPERIENCES.—Not later than 60 days after a plan is submitted to the Secretary under subparagraph (A), the Secretary shall determine whether—

"(i) the person designated to conduct the surveillance has appropriate qualifications and experience to conduct the surveillance; and

"(ii) the plan will result in the collection of useful data that will disclose adverse dietary supplement experiences or other information necessary to protect the public health.

"(3) SURVEILLANCE PERIOD.—In consultation with a manufacturer of a dietary supplement that is required to conduct surveillance under paragraph (1), the Secretary may by order require a prospective surveillance period for the manufacturer of not more than—

"(A) 3 years; or

"(B) such longer period as may be determined—

"(i) by agreement between the Secretary and the manufacturer; or

"(ii) if the Secretary and the manufacturer cannot agree, through a dispute resolution process established by the Secretary by regulation.

"(d) SAFETY REVIEW FOR POSSIBLY DANGEROUS DIETARY SUPPLEMENTS.—

"(1) IN GENERAL.—If a clinical evaluation by the Secretary of 1 or more serious adverse events indicates that a dietary supplement or a dietary ingredient contained in a dietary supplement appears to present a significant or unreasonable risk of illness, the Secretary may require the manufacturers of the dietary supplement, or of a dietary ingredient contained in a dietary supplement, to submit to the Secretary data demonstrating that the dietary supplement containing the dietary ingredient is safe.

"(2) APPROVAL OR DISAPPROVAL OF CONTINUED MARKETING.—As soon as practicable after receiving data required under paragraph (1), the Secretary shall review the data and issue a determination that—

"(A)(i) the dietary supplement is safe; and

"(ii) the continued marketing of the dietary supplement is approved; or

''(B)(i) the dietary supplement is not safe or has not been shown to be safe under ordinary or frequent conditions of use; and

''(ii) the continued marketing of the dietary supplement is disapproved.''.

(b) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(hh) ADVERSE DIETARY SUPPLEMENT EXPERIENCES.—

''(1) FAILURE TO COMPLY.—The failure of a person to submit a report or comply with any other requirement under section 416.

''(2) DISAPPROVAL OF CONTINUED MARKETING.—The continued marketing of a dietary supplement by any person after the Secretary issues a determination under section 416(d)(2)(B) that—

''(A) the dietary supplement is not safe or has not been shown to be safe under ordinary conditions of use; and

''(B) the continued marketing of the dietary supplement is disapproved.''.

SEC. 3. STIMULANTS.

(a) DEFINITION OF STIMULANT.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

''(nn) STIMULANT.—The term 'stimulant' means a dietary ingredient that has a stimulant effect on the cardiovascular system or the central nervous system of a human by any means, including—

''(1) speeding metabolism;

''(2) increasing heart rate;

''(3) constricting blood vessels; or

''(4) causing the body to release adrenaline.''.

(b) PREMARKET APPROVAL.—Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) (as amended by section 2(a)) is amended by adding at the end the following:

''SEC. 417. STIMULANTS.

''(a) IN GENERAL.—No person shall introduce or deliver for introduction into interstate commerce a dietary supplement containing a stimulant unless an approval of the dietary supplement under this section is in effect.

''(b) APPROVAL.—The Secretary shall approve an application for premarket approval of a dietary supplement containing a stimulant if the manufacturer of the stimulant demonstrates that the dietary supplement is safe under ordinary or frequent conditions of use.

''(c) COMBINATIONS OF STIMULANTS.—In the case of a dietary supplement that contains a combination of stimulants, the Secretary, in determining the safety of the dietary supplement, shall consider the interaction of the various stimulants contained in the dietary supplement.

''(d) ACTION ON APPLICATION.—The Secretary shall approve or disapprove an application for premarket approval of a dietary supplement containing a stimulant not later than 180 days after receiving the application.''.

(c) ADULTERATED FOOD.—Section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) is amended by adding at the end the following:

''(i) DIETARY SUPPLEMENTS CONTAINING A STIMULANT.—If the food is a dietary supplement containing a stimulant for which the Secretary has not granted premarket approval under section 417.

''(j) EFFECT OF SECTION.—Nothing in this section affects any other law (including a regulation) applicable to caffeine used as a food or drug.''.

(d) REGULATIONS.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance for implementing the amendments made by this section.

(e) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in paragraph (2), the amendments made by this section—

(A) apply to dietary supplements manufactured before, on, or after the date of enactment of this Act; and

(B) take effect on the date that is 180 days after the date of enactment of this Act.

(2) ALREADY-MARKETED DIETARY SUPPLEMENTS.—The amendments made by this section do not apply to a dietary supplement that has been marketed before the date of enactment of this Act until the date that is 2 years after the date of enactment of this Act.

SEC. 4. STEROID PRECURSORS.

(a) FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Section 201(ff)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff)(1)) is amended by striking ''(other than tobacco)'' and inserting ''(other than tobacco or a product that bears or contains an anabolic steroid (including a substance that is chemically and pharmacologically related to testosterone but not including an estrogen, progestin, or corticosteroid))''.

(b) CONTROLLED SUBSTANCES ACT.—

(1) DEFINITION OF ANABOLIC STEROID.—Section 102(41)(A) of the Controlled Substances Act (21 U.S.C. 802(41)(A)) is amended—

(A) by striking ''that promotes muscle growth, and includes—'' and inserting ''that promotes muscle growth or is advertised or used to promote muscle growth.

''(B) The term 'anabolic steroid' includes—''; and

(B) by striking ''(B)(i)'' and inserting ''(C)(i)''.

(2) EXCLUSION FROM SCHEDULE.—Section 201(g)(1) of the Controlled Substances Act (21 U.S.C. 811(g)(1)) is amended by striking ''if such substance'' and all that follows and inserting ''if the substance—

''(A) is approved as being safe and effective for its intended use under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355); or

''(B) is lawfully marketed under an over-the-counter monograph issued by the Food and Drug Administration.''.

SEC. 5. AGENCY EXPERTISE AND AUTHORITY.

Section 402(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(f)(1)) is amended by striking the matter following subparagraph (D).

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